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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/529,722 | 04/19/2000 | DAVID J SQUIRRELL | 124-765 | 3335 |

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

| EXAMINER | |
|---|---|
| STEADMAN, DAVID J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1656 | |

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/529,722 | SQUIRRELL ET AL. | |
| | Examiner | Art Unit | |
| | David J. Steadman | 1656 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *107-135* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *107-135* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/5/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



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## DETAILED ACTION

### *Status of the Application*

**[1]** The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

**[2]** Claims 107-135 are pending in the application.

**[3]** Applicants' amendment to the claims, filed on 8/5/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

**[4]** Receipt of an information disclosure statement (IDS), filed on 8/5/2005, is acknowledged.

**[5]** Applicants' arguments filed on 8/5/2005 have been fully considered and are deemed to be persuasive to overcome some of the objections and/or rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

**[6]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

### *Information Disclosure Statement*

**[7]** All references cited in the IDS filed on 8/5/2005 have been considered by the examiner. A copy of Form PTO-1449 is attached to the instant Office action.

### *Claim Objections*

**[8]** Claims 117 and 125 are objected to in the recitation of "anenylate kinase," which should be amended to read "adenylate kinase."

***Claim Rejections - 35 USC § 112, Second Paragraph***

**[9]** The rejection of claims 108-109, 111, 115-116, 120-135 as being indefinite in the recitation of "Photinus pyralis luciferase which has a mutation at position 354," "Luciola luciferase with a mutation at position 354," "Luciola luciferase in which the amino acid at the 217 position," and "amino acid 87 or 107 in the sequence of *E. coli* adenylate kinase" is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue "these proteins are known in the art and the meets and bounds of the claimed invention will be understood." Applicants rely on the references of WO 95/25798 and EP 524448 in support of their argument that the prior art teaches the recited sequences.

Applicants' argument is not found persuasive. A skilled artisan recognizes that identifying a specific amino acid by position number depends upon the reference sequence. While the examiner acknowledges that certain prior art documents teach an amino acid sequence of a Photinus pyralis luciferase, certain Luciola luciferases, and an *E. coli* adenylate kinase, depending upon the amino acid numbering used in a particular reference sequence, the amino acid at the recited position in any Photinus pyralis luciferase, any Luciola luciferases, and any *E. coli* adenylate kinase may not correspond to the *intended* amino acid. For example, some prior art references may disclose the amino acid numbering of a sequence beginning at the first amino acid of a signal

sequence, while other references may not include the signal sequence in their numbering. In this case, the specification fails to expressly identify the sequences of a Photinus pyralis luciferase, a Luciola luciferase, and an *E. coli* adenylate kinase such that a skilled artisan would recognize the reference sequence used to establish the amino acid at the recited position. As such, it is suggested that applicants identify the intended reference sequence of a Photinus pyralis luciferase, a Luciola luciferase, and an *E. coli* adenylate kinase.

**[10]** The rejection of claim 127 as being indefinite in the recitation of "particular different antibiotic resistance genes" is maintained for the reasons of record and the reasons stated below. While applicants argue "the claims have been revised in response to the Examiner's comments," no such revision has been made to the claim.

***Claim Rejections - 35 USC § 112, First Paragraph***

**[11]** Claims 117-119, 125-127, and 133-135 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which

applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description."

Applicants have failed to show support for the claim limitations of amended claims 117 (claim(s) 118-119 dependent therefrom), 125 (claim(s) 126-127 dependent therefrom), and 133 (claim(s) 134-135 dependent therefrom). Applicants are invited to show support for the amended claims.

**[12]** The new matter rejection of claims 108-109, 115-116, and 120-135 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the assessment of the disclosure of WO 95/25798 appears to be contrary to the Office's examination of the related US application, which issued as US Patent 6,132,983. Applicants argue the Office has examined the disclosure of WO 95/25798 and found that it enables and describes the claimed luciferase polypeptides.

Applicants' argument is not found persuasive. The issue is not whether WO 95/25798 or the corresponding US application describes and enables the luciferase polypeptides claimed therein. The issue is whether the instant application as originally filed provides support for the following recited limitations: "Photinus pyralis luciferase which has a mutation at position 354," "Luciola luciferase with a mutation at position 354," and "Luciola luciferase in which the amino acid at the 217 position is mutated to a hydrophobic amino acid." MPEP 2163.06 states, "[n]o amendment shall introduce new

matter into the disclosure of the invention." Here, the examiner has taken the position that the originally filed application fails to support the limitations as noted above.

Applicants are requested to direct the examiner's attention to such support in the original specification and/or claims.

**[13]** The written description rejection of claims 107-135 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicant again relies upon the disclosure of US Patent 6,132,983, which issued from the corresponding national stage application of WO 95/25798. Applicants argue the examiner's assessment of WO 95/25798 with respect to the written description requirement appears to be inconsistent with the Office's issuance of US Patent 6,132,983. Applicants note the claims of US Patent 6,132,983 are presumed valid.

Applicants' argument is not found persuasive. The examiner has not questioned the validity of the claims of the '983 patent. Here, the issue is not whether the claims of the '983 patent satisfy the written description requirement, but whether the claims of the instant application satisfy said requirement. However, for the sake of argument, it is noted that the genus of luciferase polypeptides and corresponding encoding nucleic acids of the claims of the '983 patent are limited by a common structural feature or features. In contrast, the genus of luciferase polypeptides and corresponding encoding nucleic acids of the claims of the instant application are, with the exception of a single amino acid substitution in certain of the claims, not limited to having any common structural feature(s). In this case, the species disclosed in European Patent Application

No. 92 1 10808.0 and WO 95/25798 fail to represent the structural variation among the members of the genus, which encompasses species that are widely variant with respect to their structures. Even assuming *arguendo* the luciferase polypeptides/encoding nucleic acids of the claims of the instant application were limited to those as recited in the '983 patent, it is noted that the conclusions based on the allowed claims of the '983 patent, unrelated by priority lineage, are not justified and are not considered to be pertinent to the determination of whether the claims satisfy the written description requirement. Applicant is reminded that each patent application is examined on its own merits. It should also be noted that applicants fail to address the lack of adequate written description of the genus of mutant adenylate kinase enzymes/nucleic acids.

**[14]** The scope of enablement rejection of claims 107-135 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the claimed invention requires a combination of elements that were allegedly well-known or obtainable by mere routine experimentation at the time of the invention, relying on the references of Ye et al., Kajiyama et al., Lowe et al., EP 052448, US Patent 6,132,983, Squirrell et al., Belinga et al., Gilles et al., and Liang et al. Applicants argue that they should not be required to describe that which was known in the art and should not be required to provide a more detailed description of the additional species encompassed by the claims.

Applicants' argument is not found persuasive. The examiner acknowledges applicants' cited teachings of the references of Ye et al., Kajiyama et al., Lowe et al., EP 052448, US Patent 6,132,983, Squirrell et al., Belinga et al., Gilles et al., and Liang et

al. However, the examiner maintains the position that the specification, even in view of the teachings of the prior art, fails to enable the full scope of the claimed invention without undue experimentation.

According to applicants, it appears that the specification, in view of the teachings of the prior art, would enable a skilled artisan to make any thermostable luciferase polypeptide/encoding nucleic acid as encompassed by the claims. Applicants argue the wild-type sequence of *Photinus pyralis* luciferase is disclosed by Ye et al., which discloses a *Photinus pyralis* luciferase polypeptide having 550 amino acids. As a representative example, the scope of claim 115 encompasses a recombinant cell expressing a mutant thermostable *Photinus pyralis* luciferase polypeptide having a mutation at position 354 and any other mutation, including any combination of deletion, insertion, addition, and/or substitution of any number of amino acids of the *Photinus pyralis* luciferase polypeptide sequence. According to applicants, making the full scope of mutant thermostable *Photinus pyralis* luciferase polypeptides is routine in the art. However, the examiner strongly disagrees. While it may be routine to generate single or even double amino acid mutants in a given polypeptide sequence, it is not routine to alter every amino acid within a given sequence with any of the 19 other common amino acids in order to isolate those that have the desired activity/utility. It should be noted that this example focused on a single polypeptide, *i.e., Photinus pyralis* luciferase. However, claim 113 is not limited to any particular luciferase and instead the claim broadly encompasses any mutant of any luciferase polypeptide that has the desired thermostability. Given the broad scope of the claims, the lack of guidance and working

examples, the high level of unpredictability in the art as evidenced by Branden et al. and Witkowski et al., which is undisputed by applicants, and the amount of experimentation, undue experimentation is required for a skilled artisan to make the full scope of the claimed invention.

***Claim Rejections - 35 USC § 103***

**[15]** The rejection of claims 107-108, 110-115, and 120-124 under 35 U.S.C. 103(a) as being unpatentable over Backman et al., Squirrell (1), Squirrell (2), and Gilles et al. is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the examiner has combined the references through an inappropriate use of hindsight. Attacking the reference of Backman et al., applicants argue that Backman et al. does not teach luciferase production, does not require engineering of host cells to produce a mutant thermostable protein, and does not teach or suggest simultaneous production of a mutant thermostable protein and a mutant thermolabile protein. Thus, according to applicants, in view of these deficiencies, one of ordinary skill in the art would not combine the cited references with Backman et al.

Applicants' argument is not found persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time

the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

At the time of the invention, the use of elevated temperature to purify luciferase from adenylate kinase activity was well-known in the art as evidenced by Squirrell et al. (1). As noted in the prior Office action, the reference of Squirrell et al. (1) suggests the use of elevated temperature to inactivate adenylate kinase activity in a preparation of luciferase. These teaching appears to be undisputed by applicants. However, while Squirrell et al. (1) clearly suggests the use of elevated temperature to inactivate adenylate kinase, the reference does not expressly teach inactivating a "thermosensitive" adenylate kinase in a preparation of a "thermostable" luciferase. The reference of Gilles et al. teaches an *E. coli* host cell that expresses an *E. coli* adenylate kinase that is inactivated at a temperature at which the luciferase of Squirrell et al. (2) remains active. Squirrell et al. (2) teaches *E. coli*-compatible vectors encoding a "thermostable" luciferase that remains active at a temperature at which the adenylate kinase of Gilles et al. is inactivated. Squirrell et al. (2) further teaches recombinant expression of the "thermostable" luciferase using *E. coli* as an expression host. Backman et al. teaches a method of recombinantly expressing a "thermostable" protein followed by heat inactivation of a contaminating undesired protein that is a consequence of recombinant expression of the desired protein. These teachings appear to be undisputed by applicants. One of ordinary skill in the art, at the time of the invention would have used the *E. coli* host of Gilles et al. for recombinant production of the

thermostable luciferase of Squirrell et al. (2) and then treated the resulting recombinant luciferase preparation at an "elevated ambient temperature" to inactivate the adenylate kinase activity as suggested by the methods of Squirrell et al. (1) and Backman et al.

In this case, the examiner has not solely relied upon the teachings of Backman et al. in making the rejection. Instead, it is the combination of teachings, as summarized above, that would have made the claimed invention obvious to one of ordinary skill in the art at the time of the invention. Applicants are reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

**[16]** The rejection of claims 117-119 and 125-127 under 35 U.S.C. 103(a) as being unpatentable over Backman et al. in view of Squirrell (1), Squirrell (2), and Gilles et al. as applied to claims 107-108, 110-115, and 120-124 above, and further in view of Novagen 1997 Catalog and Kiel et al. is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the cited references would not motivate an ordinarily skilled artisan to make the claimed invention because, according to applicants, the references are non-analogous art.

Applicants' argument is not found persuasive. In response to applicant's argument that the cited references are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned,

in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, all of the cited references pertain to the claimed invention. The reference of Backman et al. is concerned with heat inactivation of a thermosensitive contaminant protein in a preparation of a recombinant protein. Squirrell et al. (1) discusses adenylate kinase as a contaminating protein in a preparation of luciferase and the use of elevated temperature to remove adenylate kinase activity. Although applicants assert Squirrell et al. teaches thermosensitive luciferases, one of ordinary skill in the art would recognize that, by Squirrell et al. teaching that adenylate kinase activity can be inactivated in a preparation of luciferase by elevated temperature, the luciferase must necessarily be more thermostable than the adenylate kinase. Also, Squirrell et al. (2) clearly discloses "thermostable" luciferase polypeptides. Gilles et al. teaches an *E. coli* host that endogenously expresses a mutant temperature-sensitive adenylate kinase. Novagen 1997 Catalog teaches a system for recombinant production of proteins using *E. coli* as an expression host. Kiel et al. teaches a method for disrupting an endogenous gene in an *E. coli* cell that can be applied to the host as taught by Novagen 1997 Catalog. Clearly, one of ordinary skill in the art would recognize that all of the cited references are pertinent to the claimed invention. If applicants maintain their position that the references are non-analogous art, the examiner requests that applicants expressly state how the cited references are unrelated to applicants' endeavor or invention.

**[17]** The rejection of claims 107, 109-114, 116, and 128-132 under 35 U.S.C. 103(a) as being unpatentable over Backman et al. in view of Squirrell (1), Kajiyama et al., and Gilles et al. is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue Backman et al. fails to teach or suggest simultaneous production of a mutant thermostable protein and a mutant thermolabile protein. Thus, according to applicants, in view of this deficiency, one of ordinary skill in the art would not combine the reference of Gilles et al. with Backman et al. Applicants further argue the thermostable luciferase of Kajiyama et al. is not amendable to the "preferred" temperatures of Backman et al. Also, applicants argue that Squirrell et al. (1) does not cure the deficiencies of the combination of Backman et al., Kajiyama et al., and Gilles et al.

Applicants' argument is not found persuasive. That Backman et al. does not specifically teach that the undesired thermolabile contaminating protein is a mutant does not make the invention nonobvious. As noted above, it is the combination of references that would have made the invention obvious to one of ordinary skill in the art at the time of the invention. The reference of Squirrell et al. (1) suggests the use of an elevated temperature to inactivate adenylate kinase activity in a preparation of luciferase. This teaching appears to be undisputed by applicants. However, while Squirrell et al. (1) clearly suggests the use of elevated temperature to inactivate adenylate kinase, the reference does not expressly teach inactivating a "thermosensitive" adenylate kinase in a "thermostable" luciferase preparation. The reference of Gilles et al. teaches an *E. coli* host cell that expresses an adenylate kinase

that is inactivated at a temperature at which the luciferase of Squirrell et al. (2) remains active. Squirrell et al. (2) teaches *E. coli*-compatible vectors encoding a "thermostable" luciferase that remains active at a temperature at which the adenylate kinase of Gilles et al. is inactivated. Backman et al. teaches a method of recombinantly expressing a "thermostable" protein followed by heat inactivation of a contaminating undesired protein that is a consequence of recombinant expression of the desired protein. These teachings appear to be undisputed by applicants. In this case, the examiner has not solely relied upon the teachings of Backman et al. in making the rejection. Instead, it is the combination of teachings, as summarized above, that would have made the claimed invention obvious to one of ordinary skill in the art at the time of the invention.

In response to applicants' argument that the luciferase of Kajiyama et al. is not amendable to the "preferred" temperatures of the method of Backman et al., it is noted that a skilled artisan, in view of the teachings of Kajiyama et al., would have recognized that temperatures used in the *working example* would inactivate a luciferase polypeptide and would not have applied such relatively extreme temperatures. It should be noted that nowhere does Backman et al. teach that only extreme temperatures can be used in the practice of the disclosed method. Instead, the method of Backman et al. expressly teaches using a temperature that is "sufficient to inactivate said unwanted contaminants but not sufficient to inactivate said thermostable enzyme" (column 2).

In view of the *combined* teachings of Backman et al. in view of Squirrell (1), Kajiyama et al., and Gilles et al., the examiner maintains the position that the

combination would have rendered the claimed invention obvious to one of ordinary skill in the art at the time of the invention.

**[18]** The rejection of claims 117-119 and 133-135 under 35 U.S.C. 103(a) as being unpatentable over Backman et al. in view of Squirrell (1), Kajiyama et al., and Gilles et al. as applied to claims 107, 109-114, 116, and 128-132 above, and further in view of Novagen 1997 Catalog and Kiel et al. is maintained for the reasons of record and the reasons stated above.

RESPONSE TO ARGUMENT: Applicants argue the references of Novagen 1997 Catalog and Kiel et al. fail to cure the deficiencies of the other cited references.

Applicants' argument is not found persuasive. The alleged deficiencies have been addressed above. While a subcombination of the references, *i.e.,* a combination of fewer than all of the cited references, may not make the invention obvious, when one considers the combination of *all* of the cited references of Backman et al., Squirrell (1), Kajiyama et al., Gilles et al., Novagen 1997 Catalog and Kiel et al., the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention.

***Conclusion***

**[19]** Status of the claims:

Claims 107-135 are pending.

Claims 107-135 are rejected.

No claim is in condition for allowance.

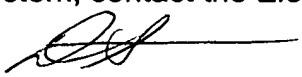
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs, 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656